



U.S. Department of Justice
Civil Division, Federal Programs Branch

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April 21, 2020

Via ECF

Hon. Paul W. Grimm
U.S. District Court for the District of Maryland
6500 Cherrywood Lane, Suite 465A
Greenbelt, Maryland 20770

Re: *American Academy of Pediatrics v. FDA*, No. 8:18-cv-883-PWG

Dear Judge Grimm:

Defendants respectfully notify the Court that on April 21, 2020, the Fourth Circuit granted a limited remand to this Court following this Court's indicative ruling (ECF No. 179). A copy of the Fourth Circuit's order is attached.

Defendants therefore respectfully submit this unopposed letter motion for an order in accordance with the Court's indicative ruling granting a 120-day extension of the premarket application deadline imposed in the Court's remedy order (ECF No. 127) in light of the global outbreak of respiratory illness caused by a new coronavirus. A proposed order is attached.

As previously noted, the requested extension is unopposed. *See* ECF No. 177. In addition, before filing this letter motion, Defendants again conferred with Plaintiffs, who authorized Defendants to represent that Plaintiffs consent to the entry of the attached proposed order, without the need for further briefing. Accordingly, Defendants respectfully urge that the Court enter the order as soon as feasible due to the need for certainty in light of the coronavirus outbreak and the upcoming May 12 deadline.¹

Defendants thank the Court for its attention to this matter.

¹ Indeed, on April 17, 2020, two of the cigar groups that are appellants here moved for a preliminary injunction in the U.S. District Court for the District of Columbia that would bar Defendants from enforcing the May 12, 2020 deadline for the submission of premarket review applications for premium cigars in light of the coronavirus pandemic. Mot. for Prelim. Inj. re COVID-19 Public Health Emergency, ECF No. 195, *Cigar Ass'n of Am. v. FDA* (D.D.C. Apr. 17, 2020). That issue should be mooted by entry of the attached proposed order.

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Respectfully submitted,

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/s/ Garrett Coyle
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